510(k) Summary

FEB - 3 2014

Date:	10 January 2014
Sponsor:	DeRoyal Industries, Inc. 200 DeBusk Lane Powell, TN 37849 USA Phone: 888.938.7828 or 865.938.7828 www.deroyal.com
Contact Person:	Nephi Zufelt, Director of Engineering and Regulatory Affairs
Trade Name:	DeRoyal Spine Spacer System
Device Classification	Class II
Classification Name:	Intervertebral body fusion device / Spinal vertebral body replacement device
Regulation:	888.3080, 888.3060
Device Product Code:	MAX, MQP
Device Description:	The DeRoyal Spine Spacer System consists of PEEK cages having the basic shape of a structural column. The top and bottom surfaces feature teeth to engage the bony endplates. The implants include a large vertical cavity which is packed with bone graft material to promote fusion of the adjacent vertebral bodies. The implants are offered in a variety of heights, widths, lengths and lordotic angles to accommodate varying patient anatomy.
Indications for Use:	Intervertebral Body Fusion Device: The DeRoyal Spine Spacers are intended for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment. The device is indicated for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the lumbar spine. Vertebral Body Replacement Device: The DeRoyal Spine Spacer System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The device system is intended for use in the thoracolumbar spine from T1 to L5. The devices are intended for use with supplemental fixation and with autograft or allograft bone. The Spine Spacer System is designed to restore biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period
Materials:	DeRoyal Spine Spacer System components are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio®) as described by ASTM F2026. Integral marker pins used in the devices are manufactured from tantalum as described by ASTM F560.

Predicate Devices: Lumbar I/F Cage® (P960025)
Lucent® (K050449, K071724 and K081968)
Eminent Spine Interbody Fusion System (K090064)
MC+ (K043479)

Performance Data: Mechanical testing of the worst case Spine Spacer was performed according to ASTM F2077 and included static and dynamic compression and static and dynamic torsion. The subsidence properties were evaluated according to ASTM F2267. Expulsion testing was performed according to the ASTM Draft Standard (29 August 2000).

The mechanical test results demonstrate that the Spine Spacer device performance is substantially equivalent to the predicate devices.

Technological Characteristics: The DeRoyal Spine Spacer System possesses the same technological characteristics as the predicate devices. These include:

- performance (as described above),
- basic design (hollow structural column),
- material (PEEK polymer and tantalum), and
- sizes (widths, lengths and heights are within the range(s) offered by the predicate).

Therefore the fundamental scientific technology of the DeRoyal Spine Spacer System devices is the same as previously cleared devices.

Conclusion: The DeRoyal Spine Spacer System devices possess the same intended use and technological characteristics as the predicate devices. Therefore the DeRoyal Spine Spacer System is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 3, 2014

DeRoyal Industries, Incorporated
% Karen Warden Ph.D.
Representative/Consultant
BackRoads Consulting, Incorporated
P.O. Box 566
Chesterland, Ohio 44026

Re: K131292
Trade/Device Name: DeRoyal Spine Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: January 10, 2014
Received: January 13, 2014

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent D. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 - Indications for Use Statement

510(k) Number: K131292

Device Name: DeRoyal Spine Spacer System

Indications for Use:

Intervertebral Body Fusion Device: The DeRoyal Spine Spacers are intended for use at one or two contiguous levels in the lumbar spine, from L2-S1, in skeletally mature patients who have had six months of non-operative treatment. The device is indicated for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the device. The device is intended for use with autogenous bone graft and with supplemental fixation systems cleared for use in the lumbar spine.

Vertebral Body Replacement Device: The DeRoyal Spine Spacer System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The device system is intended for use in the thoracolumbar spine from T1 to L5. The devices are intended for use with supplemental fixation and with autograft or allograft bone. The Spine Spacer System is designed to restore biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices